

## ORIGINAL RESEARCH

### A double-blind comparison between the conventional laparoscopic cholecystectomy and mini clipless laparoscopic cholecystectomy

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#### ABSTRACT

**Background:**Minilaparoscopy has made strong inroad to the arena of laparoscopic surgery. Gustavo Carvalho has popularized the concept and has developed a line of instruments to make the work easy. We decided to analyse the two procedures, the conventional laparoscopic cholecystectomy and the mini clipless laparoscopic cholecystectomy with the regularly available instruments. This study is done with the aim to compare the advantages and disadvantages of conventional laparoscopic cholecystectomy and mini clipless laparoscopic cholecystectomy.

**Methods:** Between June 2020 and May 2021, 102 cases of laparoscopic cholecystectomy were performed either by conventional method ( $n=51$ ) and mini clipless laparoscopic method ( $n=51$ )

**Results:** Mini clipless laparoscopic cholecystectomy had less post-operative pain ( $p < 0.05$ ), less requirement of analgesia and was a cosmetically better procedure than conventional laparoscopic cholecystectomy. Minilaparoscopy however took longer time to perform than the conventional laparoscopy ( $p < 0.05$ ). There was no significant difference in the post-operative tolerance to oral diet, duration of hospital stay, intra-operative and post-operative complications and rate of conversion between both the procedures ( $p > 0.05$ ).

**Conclusion:** Mini-clipless laparoscopy is found to be a procedure comparable to conventional laparoscopic cholecystectomy and can be advocated for routine procedure of choice in place of the conventional laparoscopic cholecystectomy as the new gold standard method with remarkable cosmetic efficiency.

**Keywords:** Conventional Laparoscopy; Minilaparoscopy; Clipless; Cosmetic

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#### INTRODUCTION

Pathology of the gall bladder and its associated structures are of many varieties. Among all these, one of the most common is calculous cholecystitis. In acute cases, there are signs of inflammation like fever, pain in the right upper quadrant of abdomen and vomiting. In chronic form, there is fibrosis and shrinkage of the gall bladder due to chronic inflammatory

process. Apart from these, there is acalculus cholecystitis, mucocele and empyema of the gall bladder, cholesterolosis of the gall bladder (strawberry gall bladder), calcification of the gall bladder wall (porcelain gall bladder) and Mirizzi's syndrome.<sup>1,2,3</sup> All of these are treated with Cholecystectomy, preferably laparoscopic way.

Statistics reflect that prevalence of gall bladder calculi is around 4.15% amongst the overall population. It is more in females (5.59%) than in males (1.99%) ( $p < 0.05$ ) in North India.<sup>4</sup> In cases of gall bladder cancer, the incidence rates (per 100,000) worldwide are in Delhi, India 21.5 % and Quito, Ecuador 12.9%. In India, prevalence of gall bladder cancer is more common in North and North-east states of India which includes Uttar Pradesh, Bihar, Orissa, West Bengal and Assam. In Assam, upper Assam districts like Dibrugarh has a high incidence of gall bladder cancer.<sup>5</sup>

For symptomatic cholelithiasis. It can be done by open and laparoscopic techniques.<sup>6</sup> Cholecystectomy is the second most common operation performed today and its founder was Carl Langenbuch. He did it in Berlin, Germany in 1882.<sup>7</sup> German Surgeon Erich Muhe performed the procedure using laparoscopic instruments thus flagging-off the modern era of cholecystectomy in 1985.<sup>8</sup> French surgeon Mouret successfully performed the laparoscopic procedure in 1987.<sup>9</sup>

Minilaparoscopy was first introduced back in 1996. Initially, it became unpopular due to expensive and delicate instruments. Reduced port size (2-3 mm) achieved greater cosmetic results and helped Minilaparoscopy to regain popularity as a cosmetic laparoscopic procedure. The addition of low friction trocars further advanced the technique. The use of electrocautery to coagulate the cystic artery and use of braided absorbable suture to tie the cystic duct made the Minilaparoscopic surgery a clipless surgery.<sup>10</sup> Meanwhile reports of Cat's eye calculus or nidus of the titanium alloy clips were reported frequently. As a result, the attention as well as the interest to clipless cholecystectomy increased. In such a situation this study was taken up with the aim to compare both the conventional laparoscopic cholecystectomy and mini clipless laparoscopic cholecystectomy to look for the better & safer alternative to the conventional laparoscopic Cholecystectomy without clips.

## AIM AND OBJECTIVES

**Aim:** This study is done with the aim to compare the advantages and disadvantages of conventional laparoscopic cholecystectomy and mini clipless laparoscopic cholecystectomy and with the following *objectives*:

1. To observe the duration of both the operations.
2. To determine the post-operative pain and requirement of analgesics (Dr. Ganguly's Score)<sup>11,12</sup>.
3. To determine the post-operative hospital stay after both the procedures.
4. To determine post-operative tolerance to oral diet.
5. To observe the post-operative cosmetic results.
6. To observe the complications at various levels
  - a) Intra-operative
  - b) Post-operative
7. To determine the conversion rate of surgery
  - a) To conventional laparoscopy
  - b) To open cholecystectomy

## MATERIALS AND METHOD

**This was a prospective double-blinded analytical study** undertaken in a Teaching Medical Institution. The study period was from June 2020 to May 2021 in which 102 patients underwent laparoscopic cholecystectomy in the department of General Surgery of Jorhat Medical College and Hospital, Assam, India. There were 25 male patients and 77 female patients. Majority of the patients were less than 40 years of age.

*Inclusion criteria* : Patients admitted to the department of General Surgery, Jorhat Medical College with cholecystitis in various stages.

*Exclusion criteria*: Patients having American Association of Anaesthesiologists Grade 3 comorbidities, pregnant females, children and patients voluntarily opting out from the study.

The patients were randomised into two groups using odd-even technique after written and informed consent was taken from each patient after explaining to them in details about the study, the operation, its benefits and risks as well as about their autonomy to opt out from the study. Each patient was provided with a patient information sheet for future reference. One group underwent conventional laparoscopic cholecystectomy ( $n=51$ ) and the other group underwent mini clipless laparoscopic cholecystectomy ( $n=51$ ). Follow-up of the patients were done at 3 weeks and 9 months.

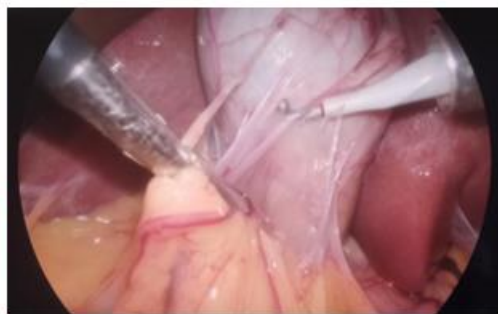
### **Operative methods**

#### **1. Conventional laparoscopic cholecystectomy (Fig. 1-6)**

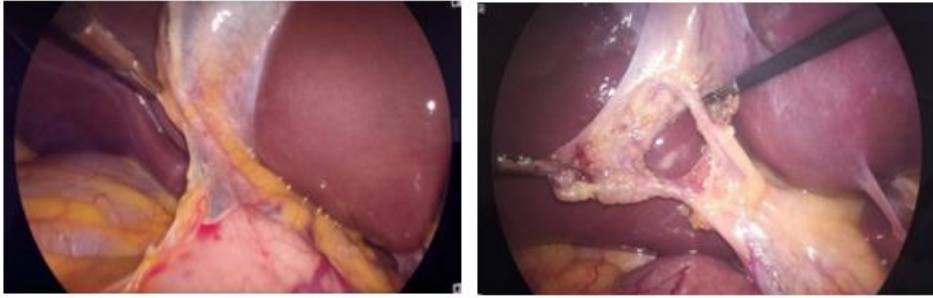
After standard positioning of the patient and the surgical team as per protocol, pneumoperitoneum was established by open Hasson's technique using a 10 mm umbilical incision. A 10 mm trocar was inserted and carbon dioxide gas was inflated to an intra-abdominal pressure of 12 mmHg.

After establishment of the pneumoperitoneum, a 30 degree/10mm optic was introduced through the umbilical trocar. Three more trocars were then inserted: a 10mm epigastric trocar was inserted for the electrocautery hook, aspirator, retrieval clamp and scissor (all these tools are of 10 mm). Two more 5 mm trocars were inserted in the right subcostal regions for the insertion of the retrieval clamps. The placements of the trocars are standardized for all the patients and followed principles of triangulation.

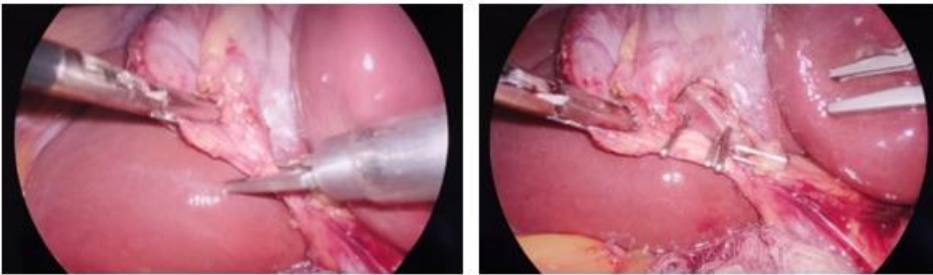
After the trocars were introduced, the abdominal cavity was examined and laparoscopic cholecystectomy was performed following the established principles of safe dissection. After dissection of the Calot' triangle, the cystic artery followed by the cystic duct were clipped. Gall bladder dissected from the liver bed and haemostasis obtained. The gall bladder was taken out through the epigastric port by using a retrieval bag which was devised from the wrist of a sterile glove. Request for an HPE was advised in all cases.



**Figure 1: Placement of ports; Figure 2: Removal of adhesions**



**Figure 3: Visualisation of the Calot's triangle; Figure 4: Critical view of safety**



**Figure 5: Clipping of the cystic artery; Figure 6: Clipping of cystic duct**

## 2. *Mini clipless* laparoscopic cholecystectomy (Fig. 7-12)

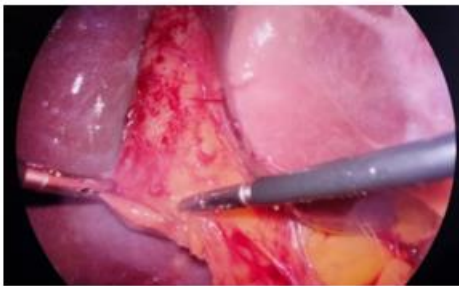
After standard positioning of the patient and the surgical team as per protocol, pneumoperitoneum was established by open Hasson's technique using a 10 mm umbilical incision. A 10 mm trocar was inserted and carbon dioxide gas was inflated to an intra-abdominal pressure of 12 mmHg.

After establishment of the pneumoperitoneum, a 30 degree/10mm optic was introduced through the umbilical trocar. Three more trocars were then inserted: a 3 mm epigastric trocar for the electrocautery hook, aspirator, retrieval clamp and scissor. Two more 3 mm trocars were inserted in the right subcostal regions for the insertion of the retrieval clamps. The placement of the trocars was standardized for all the patients and followed the principle of triangulation as in the conventional laparoscopic cholecystectomy.

After the trocars were introduced, the abdominal cavity was evaluated and after dissection of the Calot' triangle, cystic artery was identified and cauterized or ligated and cauterized distally to control it. After that cystic duct was identified, ligated with 2-0 absorbable polyglactin 9-10 suture. Two ligatures were used. 2mm apart. A retrieval bag was devised from the wrist of a sterile glove for the removal of the gall bladder. The bag is introduced in the site of 10 mm trocar following which the optic was re-introduced. The gall bladder was inserted into the bag following which the bag was guided by the most lateral clamp towards the optic trocar through which the gall bladder was removed.



**Figure 7: Placement of ports; Figure 8: Removal of adhesions**



**Figure 9: Visualisation of the Calot's triangle; Figure 10: Critical view of safety**



**Figure 11: Knotting of cystic artery; Figure 12: Knotting of the cystic duct**

We used a self-developed pain score to understand the difference in appreciation of pain in both the procedures (Ganguly's pain score)

Score of pain after surgery<sup>11,12</sup>

Grade 1. No complaints of pain after surgery. Regular course (morning dose and on patient's demand) is enough.

Grade 2. Complains of pain immediately after surgery. Needs Injectable medication. Thereafter regular dosing (night and morning dose) controls pain adequately.

Grade 3. Complains of pain Immediately. Needs injectable immediately after surgery. Thereafter repeat request every 8 hours.

**Statistical analysis**

IBM SPSS Statistics version 20 was used for the analysis of the data. All the nominal data were calculated in frequency & percentage. For nominal data analysis,  $\chi^2$  or Fischer exact test was used.



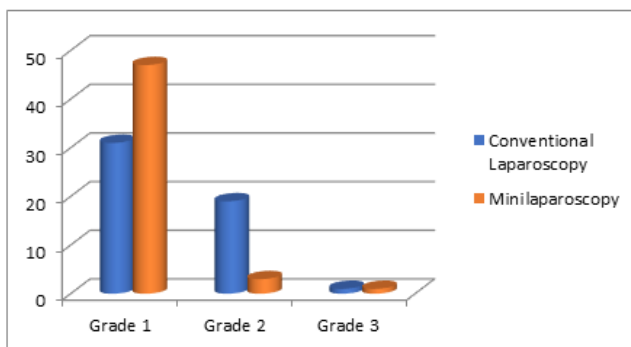
All parametric data (normal distributed) were described using mean with standard deviation. For analysis, Independent-T Test was used to compare between conventional & Mini-laparoscopy cholecystectomy.

All ordinal data or non-parametric data was described using median with IQR (Inter-quartile range). For data analysis, Mann Whitney –U Test was used.

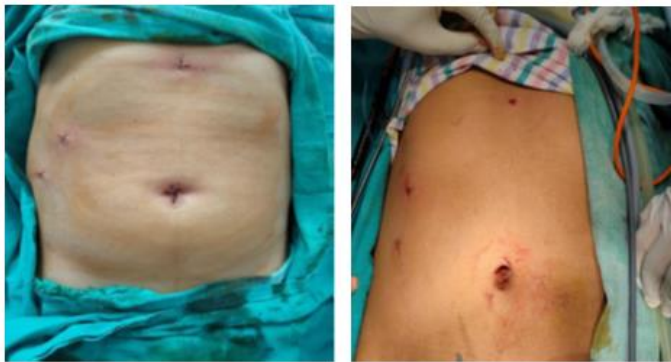
For all the data analysis,  $p$ -value  $< 0.05$  was considered to be statistically significant.

## RESULTS

The median duration time required to perform conventional laparoscopic cholecystectomy was 40 minutes and for mini clipless laparoscopy it is 65 minutes ( $p < 0.0001$ ). Mini clipless laparoscopy had less post-operative pain in comparison to conventional laparoscopy ( $p < 0.05$ ) (Fig. 13). Minilaparoscopy is also cosmetically superior compared to conventional laparoscopy (Fig.14).



**Figure 13: Grades of post-operative pain in patients.**



**a. Conventional laparoscopy(Immediate post-surgery)**

**b. Mini clipless laparoscopy(Immediate post-surgery)**



**c. Conventional laparoscopy(3 weeks post-surgery)**

**d. Mini clipless laparoscopy(3 weeks post-surgery)**

**Figure 14: (a,b,c,d): Cosmetic results**

There was no significant difference in the two procedures when compared with post-operative tolerance to oral diet (median is 6 hours for both the procedures) ( $p=0.614$ ), post-operative hospital stay ( $p=0.351$ ) and intra-operative and post-operative complications ( $p>0.05$ ).

5 cases of conventional laparoscopic cholecystectomy cases were converted to open procedure. 1 case of mini clipless laparoscopy was converted to conventional laparoscopy. The conversion rate was statistically not-significant ( $p=0.205$ ).

## DISCUSSION

This study conducted a comparative study between conventional laparoscopic cholecystectomy (umbilical and epigastric ports were of 10 mm and other two ports were of 5mm, titanium clips are used for ligation of the cystic artery and cystic duct) and mini clipless laparoscopic cholecystectomy (umbilical port is 10mm and other 3 ports are 3mm each, intracorporeal knotting with polyglactin 9-10 was used for ligation of cystic artery and duct).

Results of this study showed that mini clipless laparoscopy required slightly longer time to perform than conventional laparoscopy. However, on practice the time tends to become shorter in our series. This study was comparable with the results of the study conducted by Rikki Singalet *et al* and others in 2014 taking a sample size of 160 patients.<sup>13</sup> But Deari Ahmad Ismaeiletal(2020) and others conducted a study comparing tying and clipping of cystic artery and duct in 126 patients in which 51 patients had intracorporeal suturing and 75 patients had clipping of the cystic artery and duct. The study shows no difference in operating time in both the procedures ( $p= 0.08$ ).<sup>14</sup> Deeprasertvitet *al* (2019) and others also concluded in their study that no significant difference of operating time ( $p>0.05$ ) noted in both the procedures involving clipping and suture ligation of the cystic artery and duct in laparoscopic cholecystectomy.<sup>15</sup>

This study showed that mini clipless laparoscopic cholecystectomy had significantly less post-operative pain and also showed better cosmetic results than conventional laparoscopic cholecystectomy. The results were comparable with the following studies. Haris R. Shaikh *et al* (2017) *et al* and others concluded in their study that mini-laparoscopy has benefits over standard laparoscopy in terms of cosmetic results.<sup>16</sup> The study conducted by Dammaroet *al* and others in 2017 also showed better cosmetic results with minilaparoscopy as compared to conventional laparoscopy.<sup>17</sup> The study conducted by S. Sreenivas *et al* and others in 2014 showed that post-operative pain ( $p=0.023$ ) and requirement of analgesia ( $p=0.003$ ) was

significantly lower in the minilaparoscopy group. But the study showed no difference in length of hospital stay ( $p=0.760$ ) and complications ( $p=0.247$ ) when compared with the two procedures.<sup>18</sup> These findings were similar to the results found in our study. The intra-operative complications encountered in our study were bleeding and inadequate visualisation. The post-operative complications were pain and vomiting. This is comparable with the study conducted by J. Harju *et al* and others in 2007.<sup>19</sup> The intra-operative complications were the reasons of conversion in our study.

Use of titanium Endo clips is not required in mini clipless laparoscopic cholecystectomy as shown in this study. Thus, Endo clip complications like migration leading to obstruction of the biliary tree, pancreatitis, nidus for stone formation and injury to neighbouring structures can be avoided as concluded by the studies conducted by Kemal Dolay *et al* and others in 2007.<sup>20</sup> Use of absorbable sutures is also cost-effective as concluded by Gustavo Carvalho *et al* and others in their study in 2009.<sup>21</sup>

Our study has no difference with respect to post-operative tolerance to oral diet when both the procedures were compared. Additionally, it was found that Minilaparoscopy instruments being slender, can be manipulated easily while dissecting in the vicinity of important intra-abdominal structures.

## CONCLUSION

Thus, from the results and discussion it can be concluded that mini clipless laparoscopic cholecystectomy is probably a better operative method in certain ways than the conventional laparoscopic cholecystectomy. Though technical expertise is required for performing the clipless technique, but through exposure of more and more cases, this expertise can be acquired. This will decrease the overall operating time in performing Minilaparoscopy as result the benefit of the Minilaparoscopy can be extended to the other areas of laparoscopic procedures.

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